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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,904	09/30/2003	Cecil Kost	MMSI121562	8999

26389 7590 03/20/2006

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ART UNIT	**PAPER NUMBER**
3622	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,904	KOST ET AL.	
	Examiner	Art Unit	
	DANIEL LASTRA	3622	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,16-25,31-45 and 51-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16-25,31-45 and 51-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10, 16-25, 31-45 and 51-55 have been examined. Application 10/674,904 has a filing date 09/30/2003 and Claims Priority from Provisional Application 60/472,956 (05/22/2003).

Response to Amendment

2. In response to Non Final Rejection filed 09/16/2005, the Applicant filed an Amendment on 12/07/2005 which amended claims 1, 6, 16, 21 and 31. Applicant's amendment overcame the Section 101 rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feeney (US 2002/0032582) in view of Pham (US 2002/0065683) and further in view of Lapsker (US 4,971,362).

As per claim 1, Feeney teaches:

A *computer-implemented* system for promoting pharmaceutical drugs, comprising:

a *computer-readable* set of brand rules for guiding a distribution of drug samples of a drug (see Feeney paragraphs 283-285). Feeney target sample coupon based upon physician practice.

to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber (see Feeney paragraphs 283-285). Feeney teaches a decision engine that route marketing content based upon a physician practice, patient group; and

a computer-implemented drug sample fulfillment platform for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient (see Feeney paragraphs 282-285) but fails to teach without the use of a sales representative. However, Pham teaches a system that allows physicians to order samples via the Internet (see Pham paragraphs 118-132). Lapsker teaches the delivery of pre-printed sample vouchers to prescribers without the use of sales representative (see Lapsker figure 3, column 9, lines 35-40). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Feeney would target sample medications to physicians in the form of coupons or pre-printed vouchers, as taught by Lapsker by tracking said physicians' sample medication dispensing (see Feeney paragraph 37) and would use the Pham's system to allow said physicians to order said targeted physical sample, coupons or vouchers without the use of a sales representative (i.e. via the Internet). Feeney would have been motivated to add the Pham's feature of allowing physicians to order Lapsker's pre-printed sample vouchers without the use of sale representative in view that physicians are busier than ever and gaining access to said physicians is extremely difficult for pharmaceutical representatives. Therefore, allowing physicians to order sample products without the

use of a sale representative (i.e. via the Internet) would avoid interrupting a physician's busy schedule to deliver to said physician detailing information and sample medication.

As per claim 2, Feeney teaches:

The system of Claim 1, but fails to teach wherein drug samples include physical samples. However, teaches a online system that allows physicians to request physical samples via the Internet (see paragraph 113). Therefore, the same rejection applied to claim 1 is also applied to claim 2.

As per claim 3, Feeney teaches:

The system of Claim 1, but fails to teach wherein drug samples include a pad of pre-printed vouchers. However, Lapsker teaches a drug sample that include a pad of pre-printed vouchers. Therefore, the same argument made in claim 1 regarding this missing limitation is also made in claim 3.

As per claim 4, Feeney teaches:

The system of Claim 1, wherein drug samples include a coupon printed in the office of the prescriber, which is networked to the drug sample fulfillment platform (see paragraph 282).

As per claim 5, Feeney teaches:

The system of Claim 1, but does not expressly teach wherein the drug samples, which are in a printed form, are redeemable at a pharmacy, redeemed data being generated by the drug sample fulfillment platform for refining the brand rules so as to better guide distribution of the drug samples. However, Lapsker teaches redeeming pre-printed vouchers at a pharmacy and using said redemption to track prescriber sample

usage (see Lapkser column 7, lines 30-35). Feeney would be motivated to provide physician with the Lapsker's pre-printed sample vouchers in view that said sample vouchers would allow to identify prescribers' sample medication usage patterns which would allow Feeney to better target marketing promotions to said prescribers.

As per claim 51, Feeney teaches:

The system of Claim 1, wherein said fulfillment platform comprising:

A pharma rules sample engines for performing personalization and intelligent brand rule implementation (see paragraphs 37, 274-275; 284-285);

A marketing sample engine for integrating with drug samples suppliers and Web portals for prescribers (see paragraphs 281-282) and

The pharma rules sample engine and the marketing sample engine being based on the set of brand rules and on a set of prescriber preferences (see paragraph 258-259; 285).

As per claim 52, Feeney teaches:

The system according of claim 51, wherein the marketing sample engine links the drug sample fulfillment platform to one or more suppliers and drug samples so as to inhibit the lack of supply of sample drugs desired by the prescriber or inhibit the inconsistent supply of drug samples desired by the prescriber (see paragraph 285).

4. Claims 6-8, 10, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pham (US 2002/0065683) in view of Feeney (US 2002/0032582).

As per claim 6, Pham teaches:

A system for distributing pharmaceutical drugs, comprising:

a drug sample fulfillment platform for accessing drug sample services (see paragraph 119-132); and

a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples (see Pham paragraphs 118-132)

Pham fails to teach *if a set of brand rules which specify drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform.* However, Feeney teaches a system that targets drug sample coupons based upon prescriber practice (see paragraph 283-283). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Pham would be motivated to search for drug sample promotions, as taught by Feeney and allows prescribers to print targeted coupon via the Internet in order to better target promotions based upon prescribed medication or physician practice.

As per claim 7, Pham teaches:

The system of Claim 6, further comprising a second set of Web pages coupled to the drug sample fulfillment platform through which a sales representative can access the drug sample fulfillment platform (see paragraph 112).

As per claim 8, Pham teaches:

The system of Claim 6, but fails to teach further comprising a third set of Web pages coupled to the drug sample fulfillment platform through which a patient can access the drug sample fulfillment platform to obtain sample vouchers. However,

Feeney teaches a system that generates patients' samples electronic vouchers to allow said patients to have their sample filled at another location (see Feeney paragraph 118). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Pham would allow patients to access the Pham's sample request website to print sample vouchers, as taught by Feeney. Pham would have been motivated to add the feature of allowing patients to obtain sample vouchers via the Internet in order to allow said patients to have instant access to said sample medication with the approval of the patient's physician.

As per claim 10, Pham teaches:

The system of Claim 6, wherein the first set of Web pages display a list of the order history of the prescriber, the list including a date and a drug sample ordered by the prescriber. However, Feeney teaches a system that displays a list of the order history of the prescriber, the list including a date and a drug sample ordered by the prescriber. (see Feeney paragraph 216, 290). Pham would have been motivated to add the feature of displaying a list of the order history of the prescriber, the list including a date and a drug sample ordered by the prescriber in order to said list to better target sample medications to physicians.

As per claim 53, Pham teaches:

The system according to claim 6, but fails to teach wherein said fulfillment platform implementing a set of brand rules under which pharmaceutical drug samples are distributed, wherein said brand rules include: product; allocation quantity; sample type selected from a group consisting of live samples, pre-printed samples and on-

demand samples; and, drug strength. However, Feeney teaches a system which pharmaceutical drug samples are distributed, wherein said brand rules include: data regarding patterns distribution of drug samples and sample distribution (see Feeney paragraph 275). Pham would have been motivated to add the feature of which pharmaceutical drug samples are distributed, wherein said brand rules include: product; allocation quantity; sample type selected from a group consisting of live samples, pre-printed samples and on-demand samples; and, drug strength in order to track sample dispensing and use said tracking to better target advertisements to prescribers.

As per claim 55, Pham teaches:

The system according to Claim 6, but fails to teach wherein said fulfillment platform comprising a pharma rules sample engine for implementation brand rules under which a prescriber may obtain drug samples, the pharma rules sample engine modifying the brand rules so as to change a quantity limit of drug samples to be distributed to the prescriber. However, Feeney teaches a system where service providers change the products and the time of products to be promoted (see Feeney paragraph 285). Pham would have been motivated to add the feature of brand rules for the quantity limit of drug sample to be distributed in order to stay in budget in said sample distribution.

5. Claims 9, 16-20 and 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pham (US 2002/0065683) in view of Feeney (US 2002/0032582) and further in view of Lapsker (US 4,971,362).

As per claim 16, Pham teaches:

A drug sample fulfillment platform, comprising:

a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, an e-Detailing service, a Web site regarding a drug brand, and an online physician learning site (see paragraph 118-131); and

a request database for receiving requests of a prescriber through the drug sample Web site for drug samples, the request database responding to the prescriber (see paragraphs 118-132) but fails to teach by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers *if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical samples, or pads or pre-printed vouchers.* Feeney teaches targeting sample coupons to providers based upon physician practice (see Feeney paragraph 283) and where said sample promotions are pushed to physicians based upon said physician practice. Lapsker teaches the delivery of pre-printed vouchers to prescribers without the use of sales representative (see Lapsker figure 3, column 9, lines 35-40). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Feeney would target sample medications to physicians in the form of coupons or pre-printed vouchers, as taught by Lapsker by tracking said physicians' sample medication dispensing (see Feeney paragraph 37) and would use the Pham's system to allow said physicians to order said targeted coupons or vouchers without the use of a sales representative (i.e. via the Internet). Feeney would have been motivated to add the Pham's feature of allowing

physicians to order Lapsker's sample pre-printed vouchers without the use of sale representative (i.e. via the Internet) in view that physicians are busier than ever and gaining access to said physicians is extremely difficult for pharmaceutical representatives. Therefore, allowing physicians to order sample products without the use of a sale representative (i.e. via the Internet) would avoid interrupting a physician's busy schedule to deliver to said physician detailing information and sample medication.

As per claim 9, Pham teaches:

The system of Claim 6, but fails to teach wherein the first set of Web pages display a list of drug samples available to the prescriber to order drug samples in a form selected from a group consisting of physical samples, pre-printed vouchers, and print on-demand coupons. The same rejection applied to claim 16 is also applied to claim 9.

As per claim 17, Pham teaches:

The drug sample fulfillment platform of Claim 16, but fails to teach wherein the request database receives claim information when a patient redeems a print coupon or a preprinted voucher for physical samples. However, Feeney teaches a system that receives claim information when a patient redeems a voucher (see paragraph 52). Pham would have been motivated to add the feature of receiving claim information when a patient redeems a sample voucher for the purpose of tracking said patient redemptions and using said tracking for targeting advertisements to said patients.

As per claim 18, Pham teaches:

The drug sample fulfillment platform of Claim 17, but fails to teach wherein the request database produces a first report accounting for the number of coupons or

vouchers redeemed by patients of the prescriber. However, Lapsker teaches tracking voucher redemption (see column 5, lines 32-45). Pham would have been motivated to add the feature of accounting for the number of coupons redeem by patients, as taught by Lapsker in order to target advertisements to said patients and physicians.

As per claim 19, Pham teaches:

The drug sample fulfillment platform of Claim 18, but fails to teach wherein the request database produces a second report correlating an allocation of drug samples of a drug to the prescriber with the number of prescriptions written by the prescriber relating to the drug. However, Feeney teaches a system that generates a report that keep track of each prescriber sample dispensing (see paragraph 275). Pham would have been motivated to add the feature of keeping of track of prescriber sample dispensing in order to better target advertisements to said physicians based upon said tracking.

As per claim 20, Pham teaches:

The drug sample fulfillment platform of Claim 19, but fails to teach wherein the request database produces a third report accounting for the monetary amount spent by a pharmaceutical company on a drug sample fulfillment program for a drug and a monetary amount associated with prescriptions written by the prescriber for the drug . However, Feeney teaches a system that keeps track of drug sample dispensing by physicians and drug companies (see paragraphs 274-275). Pham would have been motivated to add the feature of accounting for the monetary amount spent by a pharmaceutical company on a drug sample fulfillment program for a drug and a

monetary amount associated with prescriptions written by the prescriber for the drug in order to know the monetary success of a sample medication and use said result to adjust marketing of said sample medication.

As per claim 31, Pham teaches:

A method for accessing a drug sample fulfillment platform, comprising:

activating a link to access the drug sample fulfillment platform from a Web portal; creating a transaction that includes a prescriber identifier and a partner identifier (see paragraph 118-132); and

mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples (see Pham paragraphs 118-132)

Pham fails to teach *only for drugs specified by a set of brand rules which include physical samples, pre-printed vouchers and print coupons*. Lapsker teaches the delivery of discount vouchers or coupon to prescribers without the use of sales representative (see Lapsker figure 3, column 9, lines 35-40). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Feeney would target sample medications to physicians in the form of coupons or vouchers by tracking said physicians' sample medication dispensing (see Feeney paragraph 37) and would use the Pham's system to allow said physicians to order said targeted coupons or vouchers without the use of a sales representative (i.e. via the Internet). Feeney would have been motivated to add the Pham's feature of allowing physicians to order Lapsker's pre-printed vouchers or coupons without the use of sale representative (i.e. via the Internet) in view that physicians are busier than ever and

gaining access to said physicians is extremely difficult for pharmaceutical representatives. Therefore, allowing physicians to order sample products without the use of a sale representative (i.e. via the Internet) would avoid interrupting a physician's busy schedule to deliver to said physician detailing information and sample medication.

As per claim 32, Pham teaches:

The method of Claim 31, further comprising formatting a set of Web pages of the drug sample Web site prior to the act of mating to emulate the look and feel of the Web portal (see paragraphs 118-132).

As per claim 33, Pham teaches:

The method of Claim 31, causing the prescriber to register if the prescriber identifier is not found in a request database (see paragraph 41).

As per claim 34, Pham teaches:

The method of Claim 31, based on a segment to which the prescriber belongs, determining one or more of the following:

what drug samples that are available to the prescriber (see paragraphs 118-132); a drug sample quantity limit that is available to the prescriber; a drug sample time limit in which the drug sample quantity limit is available; and the type of sample that is available to the prescriber.

As per claim 35, Pham teaches:

The method of Claim 34, but fails to teach receiving a selection for physical samples, the act of receiving including receiving a drug selection, a type of drug sample selection, a quantity of drug sample selection, and a delivery address (see paragraphs

258-259; 111). However, Feeney teaches receiving a drug selection, a type of drug sample selection, a quantity of drug sample selection, and a delivery address (see paragraphs 258-259; 111). Pham would have been motivated to add the feature of receiving a drug selection and quantity in order to let the system delivered the correct sample medication to a prescriber.

As per claim 36, Pham teaches:

The method of Claim 35, but fails to teach receiving a print request to print an order form capturing the drug selection, the type of drug sample selection, the quantity of drug sample selection, and the delivery address. However, Feeney teaches a system of receiving a print request to print an order form capturing the drug selection, the type of drug sample selection, the quantity of drug sample selection, and the delivery address (see Feeney see paragraph 219, 111). Pham would have been motivated to add the feature of receiving a drug selection and quantity in order to let the system delivered the correct sample medication to a prescriber.

As per claim 37, Pham teaches:

The method of Claim 36, recording the requesting activities of the prescriber in a request database (see paragraph 108).

As per claim 38, Pham teaches:

The method of Claim 34, but fails to teach receiving a selection for pre-printed vouchers or print coupons, the act of receiving including receiving a drug selection, and a quantity of coupons to be printed. The same argument made in claim 36 is made in claim 38.

As per claim 39, Pham teaches:

The method of Claim 38, but fails to teach receiving a ship request to ship the pre-printed vouchers or a print request to print coupons capturing the drug selection The same argument made in claim 36 is made in claim 39.

As per claim 40, Pham teaches:

The method of Claim 39, recording the requesting activities of the prescriber in a request database (see paragraph 31).

As per claim 41, Pham teaches:

The method of Claim 40, but fails to teach receiving a request to print a first report that lists registration data of the prescriber, the requesting activities of the prescriber, and the claim data from a claim processor that is indicative of redeemed pre-printed vouchers and print coupons at pharmacies. However, Feeney teaches a system that lists registration data of the prescriber, the requesting activities of the prescriber, and the claim data from a claim processor that is indicative of redeemed pre-printed vouchers and print coupons at pharmacies (see Feeney see paragraphs 274-275). Pham would have been motivated to add the feature of requesting activities of the prescriber, and the claim data from a claim processor that is indicative of redeemed pre-printed vouchers and print coupons at pharmacies in order to track said prescriber activities and use said tracking to target advertisements and sample medication to said prescriber.

As per claim 42, Pham teaches:

The method of Claim 40, but fails to teach receiving a request to print a second report that correlates drug samples of a drug distributed to the prescriber and with prescriptions written by the prescriber relating to the drug. However, Feeney teaches a system that prints a second report that correlates drug samples of a drug distributed to the prescriber and with prescriptions written by the prescriber relating to the drug (see Feeney paragraph 274-275). Pham would have been motivated to add the feature of that correlates drug samples of a drug distributed to the prescriber and with prescriptions written by the prescriber relating to the drug in order to track said prescriber activities and use said tracking to target advertisements and sample medication to said prescriber.

As per claim 43, Pham teaches:

The method of Claim 40, but fails to teach receiving a request to print a third report that accounts for the return on investment for a monetary amount spent on a drug sample distribution program for a drug and the monetary amount received from prescriptions for the drug. However, Feeney teaches a system that prints a third report that accounts for the return on investment for a monetary amount spent on a drug sample distribution program for a drug and the monetary amount received from prescriptions for the drug (see Feeney paragraph 274-275). Pham would have been motivated to add the feature of determining the return on investment for a monetary amount spent on a drug sample distribution program in order to track said sample distribution success and use said tracking to adjust marketing of said sample medication.

As per claim 44, Pham teaches:

The method of Claim 40, but fails to teach detecting fraud by comparing the drug sample quantity limit and the time frame in which the drug sample quantity limit is available to the prescriber and the claim data which is indicative of the number of pre-printed vouchers and print coupons redeemed by patients. However, Feeney teaches a system that detects fraud with sample medication prescription (see Feeney paragraph 284-285). Pham would have been motivated to add the feature of detecting fraud in coupon redemption in view that coupon's fraud cost companies a lot of money without said companies receiving a return in the investment of said coupons.

As per claim 45, Pham teaches:

The method of Claim 40, but fails to teach refining the drug sample quantity limit of the prescriber based on the number of redemptions of pre-printed vouchers and print coupons associated with the prescriber. However, Feeney teaches a system that refines the drug sample quantity limit of the prescriber based on the number of redemptions of pre-printed vouchers and print coupons associated with the prescriber (see Feeney paragraph 282). Pham would have been motivated to track prescriber dispensing of sample medication in order to adjust the marketing of said sample medication.

6. Claims 21, 23-25 and 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pham (US 2002/0065683) in view of Feeney (US 2002/0032582) and further in view of Thornton (US 5,628,530).

As per claim 21, Pham teaches:

A networked system for ordering pharmaceutical sample drugs, comprising:

a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink (see paragraph 118-132)

the drug sample Web site presenting a Web page including selectable options for the prescriber to order drug samples (see Pham paragraphs 118-132)

Pham fails to teach *the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules.* However, Feeney teaches in paragraph 284 a system that determines the duration of a promotion. Thornton teaches sample pre-printed vouchers with expiration date (see figure 4). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the application was made, to know that Pham would be motivated to search for drug sample promotions, as taught by Feeney and allows prescribers to print targeted coupon or pre-printed vouchers with expiration dates, as taught by Thornton via the Internet in order to better target promotions based upon prescribed medication or physician practice.

As per claim 23, Pham teaches:

The networked system of Claim 21, but fails to teach wherein the selectable options of the Web page include a quantity for each drug sample, which is specifiable by the prescriber. However, Feeney teaches a system of including a quantity of each drug sample (see paragraph 258. Pham would have been motivated to add the feature of allowing physician to indicate the quantity for each drug sample, as taught by Feeney to let the system knows the amount of the said order.

As per claim 24, Pham teaches:

The networked system of Claim 21, but fails to teach the selectable options of the Web page include a delivery location to which the drug samples will be shipped. However, Feeney teaches a system where selectable options of the Web page include a delivery location to which the drug samples will be shipped (see paragraph 111). Pham would have been motivated to add the feature of including a delivery location to which the drug samples would be shipped in order that said sample are delivered to the correct address.

As per claim 25, Pham teaches:

The networked system of Claim 21, but fails to teach wherein the selectable options of the Web page include an option for printing on-demand vouchers on a printer in the office of the prescriber. However, Feeney teaches a system that includes an option for printing on-demand coupons on a printer in the office of the prescriber (see paragraph 284) and Thornton teaches pre-printed sample vouchers (see figure 4). Pham would have been motivated to add the feature of allowing a prescriber to print sample coupons or pre-printed vouchers, as taught by Thornton in said prescriber's office for the purpose of making it easier for said prescriber to prescribe said sample medications to users.

As per claim 54, Pham teaches:

The system according to claim 6, but fails to teach wherein said fulfillment platform implementing a set of brand rules for distributing pharmaceutical drug samples, said brand rules including timing considerations that are selected from a group consisting of sample offer time limits and rolling expiration dates for vouchers from

either within or between brands for which a quantity of drug samples can be ordered However, Thornton teaches sample pre-printed vouchers with expiration date (see figure 4). Pham would have been motivated to add the feature of setting brand rules of sample offer time limits and expiration dates, as taught by Thornton in order to eliminate the dispensing of outdated sample drugs.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pham (US 2002/0065683) in view of Feeney (US 2002/0032582) and further in view of Thornton (US 5,628,530) and Lapsker (US 4,971,362).

As per claim 22, Pham teaches:

The networked system of Claim 21, but fails to teach wherein the drug samples are in a form selected from a group consisting of physical samples and pre-printed vouchers. However, the same argument regarding the limitation about physical sample and pre-printed vouchers made in claim 16 is also made in claim 22.

Response to Arguments

8. Applicant's arguments filed 12/07/2005 have been fully considered but they are not persuasive. The Applicant argues that Pham has been overcome by an Affidavit and its exhibits under 37 C.F.R. §§ 1.131. The Examiner answers the affidavit filed on 12/07/2005 under 37 CFR 1.131 has been considered but is ineffective to overcome the Pham reference. Where the conception occurs prior to the date of the reference, but reduction to practice is afterwards, it is not enough merely to allege that patent owner or applicant had been diligent. Ex parte Hunter, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of facts establishing diligence. An

applicant **must account for the entire period during which diligence is required.** Gould v. Schawlow, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); In re Harry, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964)(statement that the subject matter "was diligently reduced to practice" is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. In re Mulder, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131issue); Fitzgerald v. Arbib, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959)(Less than 1 month of inactivity during critical period. (Diligence requires that applicants must be specific as to dates and facts.). **In this case the applicant must show evidence of facts to establish diligence from July 27, 2000 to May 22, 2003, showing the works done on the invention for everyday of that period. See MPEP 2138.06.**

Furthermore, MPEP 715.02 teaches that the 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. In re Tanczyn, 347 F.2d 830, 146 USPQ 298 (CCPA 1965) (Where applicant claims an alloy comprising both nitrogen and molybdenum, an affidavit showing applicant made an alloy comprising nitrogen but not molybdenum is not sufficient under 37 CFR 1.131 to overcome a rejection under 35 U.S.C. 103 based on the combined teachings of one reference disclosing an alloy comprising nitrogen but not molybdenum and a second reference disclosing an alloy comprising molybdenum but not nitrogen). The affidavit or declaration showing must

establish possession of the invention (i.e., the basic inventive concept) and not just of what one reference (in a combination of applied references) happens to show, if that reference does not itself teach the basic inventive concept. In re Spiller, 500 F.2d 1170, 182 USPQ 614 (CCPA 1974). Applicant may overcome a 35 U.S.C. 103 rejection based on a combination of references by showing completion of the invention by applicant prior to the effective date of any of the references; applicant need not antedate the reference with the earliest filing date. However, as discussed above, applicant's 37 CFR 1.131 affidavit must show possession of either the whole invention as claimed or something falling within the claim(s) prior to the effective date of the reference being antedated; it is not enough merely to show possession of what the reference happens to show if the reference does not teach the basic inventive concept. Where a claim has been rejected under 35 U.S.C. 103 based on Reference A in view of Reference B, with the effective date of secondary Reference B being earlier than that of Reference A, the applicant can rely on the teachings of Reference B to show that the differences between what is shown in his or her 37 CFR 1.131 affidavit or declaration and the claimed invention would have been obvious to one of ordinary skill in the art prior to the date of Reference A. However, the 37 CFR 1.131 affidavit or declaration must still establish possession of the claimed invention, not just what Reference A shows, if Reference A does not teach the basic inventive concept. Furthermore, Applicant's affidavit page 2 recites that a sales representative visit with physicians, and authorize release of additional vouchers. Therefore, the Applicant needs to indicate where in the Affidavit the Applicant has support for the limitation of ordering drugs samples without the use of a

sales representative and also, where in the Applicant's affidavit there is support for the "set of brand rule" limitation, recited in the Applicant's claims. Applicant's basic inventive concept is the combination of allowing a prescriber to obtain drug samples without the use of a sales representative with the added limitation of a "set of brand rules" that would guide said obtaining, and the Applicant's affidavit does not show said basic inventive concept.

The Applicant argues that the Feeney system is centered on its ability to control the dispenser, and if Feeney cannot control the dispensers, nothing would work in Feeney.

The Examiner answers that the Examiner is using the Pham and not the Feeney reference to teach ordering sample mediation without the use of a sales representative The Feeney reference is used by the Examiner to taught the use of rules for targeting sample promotions to prescribers.

The Applicant argues that Feeney does not teach brand rules. The Examiner answers that Applicant's specification page 17, lines 20-22 recites "such rules can be based on many factors, including the speciality of the prescriber". Feeney teaches in paragraph 283 the targeting of promotions based upon physician practice. Therefore, Feeney teaches brand rules as defined by Applicant's specification.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

- Wallace teaches a system and method for drug dispensing.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL LASTRA whose telephone number is 571-272-6720 and fax 571-273-6720. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ERIC W. STAMBER can be reached on 571-272-6724. The official Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DL
Daniel Lastra
February 13, 2006

RAQUEL ALVAREZ
PRIMARY EXAMINER